

**AMENDMENT TO THE  
AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 5279  
OFFERED BY M. \_\_\_\_\_**

Page 104, after line 10, insert the following new section:

1 **SEC. 116. EXCEPTION FOR MANUFACTURERS WITH GROSS**  
2 **ANNUAL SALES UNDER \$1,000,000.**

3 The requirements of this Act and the amendments  
4 made by this Act, other than the subsections (a) and (b)  
5 of 610, section 612, and section 614 of the Federal Food,  
6 Drug, and Cosmetic Act, as added by this Act, shall not  
7 apply with respect to an entity that—

8 (1) manufactures cosmetic products or cosmetic  
9 formulations for sale or distribution in the United  
10 States; and

11 (2) has gross annual sales under \$1,000,000.

